Non-Technical Abstract. NCI No. 5633

TITLE: A Phase I Study of Sequential Vaccinations with Fowlpox-CEA(6D)-TRICOM (B7.1/ICAM/LFA3) and Vaccinia-CEA(6D)-TRICOM, in Combination with GM-CSF and Interferon-Alfa-2B in Patients with CEA Expressing Carcinomas.

In this study participants will receive a vaccine to a protein found in certain cancers (carcinoembryonic antigen or CEA). This vaccine can help increase the number of specialized immune cells (called T cells) that can find and kill cells containing CEA. After receiving the vaccine, participants will get three injections of a drug called interferon-alpha-2b, which the researchers think will increase the level of CEA in the tumor and make it more visible to the T cells. This study will help the researchers find out if there are any side effects when the vaccine is used with interferon-alpha-2b in persons with advanced cancer. This is a phase 1 study, which means that the main goal of the study is to determine the safest dose of interferon-alpha-2b to give with the vaccine. As new participants are signed up for the trial, they will be assigned to get higher and higher doses of interferon-alpha-2b. However, individual participants will receive interferon-alpha-2b at a single set dose. They will not have a choice in selecting the dose of interferon-alpha-2b that they will receive. This study will be offered to participants with advanced cancer who have already had one course of chemotherapy.

The vaccine treatment consists of 4 parts or ingredients. Part 1 is the anti-CEA vaccine. This is derived from the vaccinia virus, which is the same virus material that has been used for many years to vaccinate people against smallpox. Participants will receive this vaccine only one time. Part 2 is a second CEA vaccine that is made from a related virus, called the fowlpox virus. Participants will receive at least three injections of this second vaccine. And Part 3 is a protein called GM-CSF that boosts the immune system. Part 4 is the treatment with interferon-alpha-2b.